ARTIFICIAL IMPLANT LENS

CROSS REFERENCES TO RELATED APPLICATIONS

This application is a continuation-in-part application of copending application Ser. No. 691,712 filed on June 7, 1976, now abandoned.

BACKGROUND OF THE INVENTION

The invention relates to an implant lens made of transparent material, in particular an elastic and flexible synthetic, plastic material, for example silicone rubber, as a dioptric substitute for a natural lens which has been surgically removed from the eye of a living being. It is fitted with holders which extend radially outwards from the pupil to overlap the iris, and thus to secure the implant lens to the iris.

The nature of the cataract is the clouding of a lens of a living being. The resulting diminution of sight can only be eliminated by surgically removing the lens and then replacing it by a suitable optical material, the most commonly used substitute being the well-known cataract glasses or spectacles; in suitable cases contact lenses are also used, which fit directly against the cornea of the eye. Functionally the best substitute is an artificial lens which is inserted surgically into the eye.

It is therefore an object of the present invention to construct the lenses of the type discussed in such a way that, while retaining all their advantages and properties, they considerably facilitate the difficult task of inserting the lens into the pupil of the iris. A proper lens placement, without any change of position, is thus insured, so that the patient operated on has the same field of vision as had been provided prior to the removal of the natural lens.

This avenue was explored by the Englishman RIDLEY, who in 1949 began implanting a perspex lens into the posterior eye chamber. The expectations and hopes placed in this procedure were not fulfilled however, as experience later showed, which is why it has now been abandoned for some time. In a not insignificant number of cases, the lens slipped out of the posterior chamber and into the vitreous body therebehind. Such lenses, disposed in the wrong place, have the effect of a foreign body in the eye, are not tolerated biologically, and over a period of time represent a substantial danger to the survival of the eye.

A further possibility for a dioptric substitute for the lens removed from the eye was seen in the implantation of plastic lenses in the anterior chamber of the eye. These anterior chamber lenses, as they are called, are not placed in the physiological position, i.e., behind the iris, but at a greater or lesser distance from the latter, in the area of the anterior eye chamber. A wide variety of models of such lenses were designed and used. They came from STRAMPELLI, SCHRECK, WALSER and DANNHEIM, among others. With time, however, it became obvious that these lenses were not tolerated biologically by the eye.

In addition, lenses of transparent plastic became known (BINKHORST, WORST, etc.) which consist of a biconvex or planoconvex disc and have supports of the most varied kinds to hold the lens in place, either in the anterior chamber of the eye or in the plane of the pupil. These lenses are made of polymethacrylates and have wire or plastic loops, usually attached to the back. The plane encompassed by the loop lies behind the back surface of the artificial lens. It is held in place in the eye by insertion of the loops through the pupil of the iris so that they fit against the back surface of the iris. After the surgical insertion of the lens, the pupil is then artificially (medicinally) contracted. The mechanical support of the artificial lens is thus ensured, in that its back surface fits against the anterior surface of the iris, while the supporting loops lie against the posterior surface of the iris. In keeping with their characteristic method of fixation, these lenses are known as "clip-lenses." According to the shape of the differently designed loops, the lens may also be sutured to the iris.

Although the hitherto published results regarding these "iris clip" lenses are relatively favorable, even these do still have decisive disadvantages, which are important and substantial. Because of their specific gravity, every movement of the eye causes these lenses to experience pitching movements, which place an unwelcome mechanical stress or burden on the delicate iris tissue supporting them.

Apart from polymethacrylates, polyamides have also been used as material for such lenses. However, the disadvantage of all these materials is in particular that lenses made from them cannot be sterilized in a surgically perfect manner. To achieve a completely germless state, including killing off bacterial spores, modern surgery uses heat sterilization with hot steam or hot air. In the former of these two methods of sterilization, superheated water vapor at a temperature of 134° C. and a vapor pressure of 2.5 atu (2.5 atu=3.5 at) acts on the material to be sterilized in an autoclave for about 15 minutes; in hot air sterilization, the material to be sterilized is exposed to an artificially circulated air current at 200° C. for about 30 minutes. The lens materials which have hitherto been used cannot stand up to such stresses.

The other possibility, gas sterilization with ethylene oxide at a relatively low temperature of about 55° C., is too risky for implant lenses, because this highly reactive gas, as is generally known, cannot be controllably stored in certain substances, such as plastics, or substances containing plastics.

Sterilization by means of high-energy rays (cathode rays, beta rays, X-ray, gamma rays) must likewise be excluded in the present case, since they may cause molecular structural changes in the plastic bodies; the resultant molecular fragments are not infrequently toxic. It is now known that over a period of time, a substantially increased tendency to corrosion, with subsequent clouding of the material, occurs in radiation-sterilized acrylate lenses (PMMA).

As a result, surgery has inevitably had to make do with subjecting the implant lenses to a chemical liquid sterilization process, i.e., virtually disinfecting them, immediately after their manufacture, and then preserving them in ampoules in more or less suitable fluids. The lenses are taken out of these ampoules immediately before the operation. The limitation of chemical liquid sterilization is due, in the present case, at least by its inability to destroy bacterial spores; also, these chemicals, which are not inert, accumulate in plastic bodies, which they then leave, uncontrollably and over a long period of time, according to an exponential function. This behavior gives cause for concern, particularly for an eye implant.

A further disadvantage of the materials used for the previously known lenses is that they are polymers,